General

Guideline Title

Guidance on 1.5 tesla magnetic resonance imaging scanners compared with 3.0 tesla magnetic resonance imaging scanners.

Bibliographic Source(s)

Canadian Agency for Drugs and Technologies in Health (CADTH). Guidance on 1.5 Tesla magnetic resonance imaging scanners compared with 3.0 Tesla magnetic resonance imaging scanners. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health (CADTH); 2011 May. 4 p.

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Based on best available evidence, albeit limited, and clinical expertise, the Canadian Agency for Drugs and Technologies in Health (CADTH) Magnetic Resonance Imaging (MRI) Expert Advisory Panel developed the following statements to help provide guidance in the purchasing of 3.0 tesla (T) MRI scanners or 1.5 tesla MRI scanners:

- The best available evidence suggests that for most indications the 3.0 T MRI and 1.5 T MRI appear to be similar for clinical outcomes including safety.

The CADTH MRI Expert Advisory Panel developed the remainder of the guidance based on clinical and technical expertise of MRI technology.

When considering the potential clinical advantages or disadvantages of 3.0 T MRI compared with 1.5 T MRI, the Expert Advisory Panel provides the following statements:

- For advanced clinical neuroscience assessment and therapeutics — especially for neurovascular diseases, neuro-oncology, and epilepsy — the technical and clinical experience suggest benefit of the 3.0 T MRI compared with the 1.5 T MRI.
- 3.0 T MRI may be preferred over 1.5 T MRI for some cardiovascular applications such as myocardial perfusion and peripheral vascular angiography.
- For oncology, excluding neuro-oncology, while the visualization of small lesions is greater with a 3.0 T MRI, the clinical implications and the balance of benefits versus harms are unclear.

When considering where 3.0 T MRI technology should be applied, the Expert Advisory Panel provides the following statements:

- 3.0 T MRI should be applied where the enhanced diagnostic capacity of 3.0 T MRI will support clinical programs.
- 3.0 T MRI requires greater clinical expertise and paramedical personnel support for its operation.
- There may be synergies by locating a 3.0 T MRI where there is research capacity.

When considering whether a 3.0 T MRI can function as a stand-alone unit, without on-site 1.5 T MRI back-up, the Expert Advisory Panel provides the following statements:

- Any decision about placement of a 3.0 T MRI or a 1.5 T MRI should be made with consideration given to the clinical services being delivered.
- While theoretically the 3.0 T MRI could operate as a stand-alone unit, current practice would suggest that it be partnered with 1.5 T MRI to better serve the full spectrum of patients.

Of Note:

- The Expert Advisory Panel recognizes the existence of comparative evidence supporting improved image quality with 3.0 T MRI over 1.5 T MRI. The Expert Advisory Panel also recognizes that there is a lack of high-quality comparative evidence linking improved image quality to improved diagnoses, patient management, and clinical outcomes.
- 3.0 T MRI may not be suitable for some patients because of inherent artifacts and because some implanted devices are not yet approved in the 3.0 T MRI environment.
- Adherence to established safety protocols should mitigate any patient safety concerns associated with 3.0 T MRI.
- As MRI is a rapidly advancing technology with long-term service delivery commitment, future decisions regarding 3.0 T MRI or 1.5 T MRI for other clinical indications may require reconsideration as further evidence and clinical experience become available.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Diseases or conditions requiring magnetic resonance imaging (MRI)

Guideline Category

Diagnosis

Evaluation

Technology Assessment

Clinical Specialty

Cardiology

Family Practice

Internal Medicine

Neurological Surgery

Neurology

Oncology

Orthopedic Surgery

Radiology

Intended Users

Advanced Practice Nurses

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To help health care decision-makers, patients, health care professionals, health systems leaders and policy-makers make well-informed decisions and thereby improve the quality of health care services
- To help provide guidance in the purchasing of 3.0 tesla (T) magnetic resonance imaging (MRI) scanners or 1.5 T MRI scanners for health care decision-makers, patients, health care professionals, health systems leaders and policy-makers

Target Population

Canadian adults and children with conditions or diseases requiring magnetic resonance imaging (MRI)

Interventions and Practices Considered

Magnetic resonance imaging (MRI) using either a 1.5 tesla (T) MRI scanner or a 3.0 T MRI scanner

Major Outcomes Considered

- Impact on diagnosis, clinical management decisions, or patient outcomes
- Clinically meaningful measures, e.g., categorized lesions, measured degree of stenosis, measured amount of muscle damage
- Safety

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Research Questions

The purpose of the systematic review (see the "Availability of Companion Documents" field) is to evaluate the differences between 1.5 T MRI and 3.0 T MRI scanners. The research questions are:

1. What are the clinical benefits, limitations, and safety considerations for imaging with a 1.5 T MRI scanner compared with a 3.0 T MRI scanner?
2. What are the service delivery, personnel, and structural (renovation, installation) differences between a 1.5 T MRI scanner and a 3.0 T MRI scanner?

Literature Search Strategy

All peer-reviewed search strategies were developed by the Information Specialist (CS), with input from the project team. Published, peer-reviewed literature was searched using the following bibliographic databases: MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, MEDLINE daily, and EMBASE via Ovid. The CINAHL database was searched via EBSCO. Parallel searches were run in PubMed and The Cochrane Library (Issue 11, 2010).

The search strategy comprised controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Methodological filters were applied to limit the retrieval of articles on 1.5 tesla (T) magnetic resonance imaging (MRI) systems or 3.0 T MRI systems to health technology assessments (HTAs), systematic reviews, and meta-analyses. No filters were applied to limit the retrieval by study type for articles that compared 1.5 T MRI systems and 3.0 T MRI systems. Appendix 2 in the systematic review (see the "Availability of Companion Documents" field) shows the detailed search strategies. The search was restricted to articles that were published in English or French between January 1, 2005 and November 29, 2010. Regular alerts were established on MEDLINE, EMBASE, PubMed, and CINAHL, current to April 27, 2011. Grey literature was identified by searching the websites of Health Technology Assessment (HTA) and related agencies, professional associations, and other specialized databases. Google and other Internet search engines were used to search for more information. These searches were supplemented by hand-searching the bibliographies and abstracts of key papers, and through contact with appropriate experts and agencies.

Selection Criteria

Two reviewers independently assessed the results of the literature search and selected citations that seemed to satisfy the inclusion criteria. Through consensus, potentially relevant citations were identified and full-text articles were retrieved. All potentially relevant full-text articles presenting harms data were selected. In addition, citations for relevant review articles were selected for background information. The potentially relevant studies were classified into six clinical areas:

- Neurology
- Cerebrovascular conditions
- Renal artery stenosis
- Coronary artery disease (CAD)
- Musculoskeletal disorders
- Oncology

The six clinical groups were divided between two reviewers and the selection criteria (see Table 2 in the Systematic Review [see the "Availability of Companion Documents" field]) were applied again by both reviewers. Disagreements were resolved by consensus, without the need for a third party.

Information Gathering to Address Research Question No. 2

To address the service delivery, personnel, and structural differences between 1.5 T MRI and 3.0 T MRI scanners, information was drawn from several relevant review articles that were identified in the initial literature search, information from web-based sources, and Original Equipment Manufacturer (OEM) materials. In addition, a questionnaire was sent to the five OEMs marketing MRI in Canada. The 11 questions addressed topics such as requests for clinical and economic study information; identification of evidence-based MRI guidelines; key elements of the OEM's top-of-the-line 1.5 T MRI and 3.0 T MRI scanners; differences between the technologies, costs, and options available; clinical benefits, limitations, and safety of 1.5 T MRI and 3.0 T MRI from the OEM's perspective; typical annual operating costs; and typical scan room renovation costs.

Safety in Infants, Pediatric Populations, and Adults Methods

Relevant articles reporting on safety outcomes were identified from the clinical literature search for the main report. In addition, a focused search was conducted in PubMed for articles in which the main concepts appeared in the title or as a major subject heading. The search was limited to English or French language documents published between January 1, 2005 and February 11, 2011. No filters were applied to limit retrieval by study type. Studies were eligible for inclusion if they met the criteria outlined in Table 1 in the "Supplemental Issues" section of the systematic review (see the "Availability of Companion Documents" field). Simulation studies performed on "phantoms," cadavers, or animals were excluded.

Number of Source Documents

The systematic review included 25 studies that reported on various clinical test parameters of 1.5 tesla (T) magnetic resonance imaging (MRI) compared with 3.0 T MRI.

The supplemental safety review identified 18 studies (1.5 T MRI and/or 3.0 T MRI).

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction Strategy for the Systematic Review

The included studies were reviewed and data entered into evidence tables created by each author for his or her clinical categories under the following headings: study, patient population, imaging procedure (intervention methods), relevant outcomes (magnetic resonance imaging [MRI] measures), and findings relevant to the clinical situation (see Appendix 3 in the systematic review [see the "Availability of Companion Documents" field]). The second clinical reviewer then checked the work of the lead reviewer for each category.

Strategy for Validity Assessment of Studies for the Systematic Review

Studies were assessed for validity by patient outcome; that is, changes in clinical outcomes, patient management, or diagnosis (see Table 3 in the systematic review document). Studies that reported clinical test parameters were included, whereas studies that reported only technical test parameters were excluded.

Safety in Infants, Pediatric Populations, and Adults Methods

Data were extracted from the studies that met the inclusion criteria and were summarized in evidence tables and discussed narratively.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

In developing the guidance, the Canadian Agency for Drugs and Technologies in Health (CADTH) Magnetic Resonance Imaging (MRI) Expert

Advisory Panel considered the following:

- A systematic review examining evidence as to the comparative clinical effectiveness (that is, benefits and safety) and limitations of 1.5 tesla (T) MRI and 3.0 T MRI scanners
- A supplemental narrative review of published evidence on the safety of 1.5 T MRI or 3.0 T MRI for all clinical applications. This review extended the evidence base from the systematic review by summarizing primary studies, widened the patient population to healthy volunteers, and addressed safety for pediatric populations and patients with implanted devices.
- Manufacturer information
- Clinical and technical expertise
- Public values and preferences

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The guidance report and the systematic review with the supplemental review of safety and manufacturer information were posted for public comment on March 24, 2011.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The guidance was based on the best available evidence, and clinical and technical expertise.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- This guidance may aid decision-making for Canadian jurisdictions considering the purchase of a 1.5 tesla (T) magnetic resonance imaging (MRI) scanner or a 3.0 T MRI scanner.
- Increased clinical applications in the short- and long-term may be possible with access to 3.0 T MRI scanners.
- While there is a lack of studies assessing how 3.0 T MRI benefits patient diagnoses, patient management, and clinical outcomes, the Expert Advisory Panel indicated that local availability of a 3.0 T MRI may improve patient care in selected cases by reducing the need for multiple diagnostic tests, and reducing patient travel to access 3.0 T MRI located at a more distant site or outside the province of residence.

Potential Harms

The supplemental review of safety identified 18 studies; all supported the safety of both field strengths in pediatric populations, as well as patients with implanted devices. One study suggested that the core temperature of children may be increased with 1.5 tesla (T) magnetic resonance imaging (MRI) and 3.0 T MRI scanning. The authors of this study suggested continuous monitoring of temperature during MRI, especially in children with fever or who were critically ill, but did not discuss these findings in relations to the risk of burns. A subsequently identified study concluded that 3.0 T MRI was not associated with an increased change in temperature in a pediatric population.

Additional points related to harms (note: this section is taken from a review of harms information in the literature and not from the individual studies that were assessed in the systematic review, where harms were not reported):

- The 5 Gauss (0.0005 T) magnetic field that is associated with 1.5 T MRI and 3.0 T MRI systems is usually confined to the scanning room walls by using active magnetic shielding. However, the attraction of ferromagnetic objects that are inadvertently placed near a scanner will exhibit an abrupt pull from a 3.0 T magnet compared to a gradual pull with a 1.5 T magnet.
- Pulsed radiofrequency fields can induce currents resulting in heating of the body and, depending on the situation, cause patient burns.
- The noise level of 3.0 T MRI scanning approaches twice that of 1.5 T MRI scanning and, depending on the pulse sequence used can be in excess of 130 decibels. Although manufacturers have incorporated sound-dampening material, patients using 3.0 T MRI scanning must use hearing protection.

Contraindications

Contraindications

Patients with implants and devices that have elongated configurations or that form conducting loops should not undergo 3.0 tesla (T) magnetic resonance imaging (MRI) scanning until ex vivo heating has been assessed to determine the relative risks. For example, a new generation of pacemakers was released in 2011 which is currently only 1.5 T compatible. A resource for determining the status of devices and MRI can be found at www.MRIsafety.com. This web site provides a list of implants, devices, materials, and other products, divided into categories to facilitate access and review of pertinent information.

Qualifying Statements

Qualifying Statements

- The information in this report should not be used as a substitute for the application of clinical judgment in respect of the care of a particular patient or other professional judgment in any decision making process nor is it intended to replace professional medical advice. While the Canadian Agency for Drugs and Technologies in Health (CADTH) has taken care in the preparation of the report to ensure that its contents are accurate, complete and up-to-date, CADTH does not make any guarantee to that effect. CADTH is not responsible for any errors or omissions or injury, loss, or damage arising from or as a result of the use (or misuse) of any information contained in or implied by the information in this report.
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Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Canadian Agency for Drugs and Technologies in Health (CADTH). Guidance on 1.5 Tesla magnetic resonance imaging scanners compared with 3.0 Tesla magnetic resonance imaging scanners. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health (CADTH); 2011 May. 4 p.

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 May

Guideline Developer(s)

Canadian Agency for Drugs and Technologies in Health - Nonprofit Organization

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Guideline Committee

Magnetic Resonance Imaging (MRI) Expert Advisory Panel

Composition of Group That Authored the Guideline

Panel Members: Dr. Jean Gray (*Chair*); Dr. Martin Charron; Mr. Harlon Davey (*public member*); Dr. Alexander Dick; Dr. Darren Ferguson; Dr. Scott Klarenbach; Dr. Andre le Roux; Dr. Lindsay Nicolle; Dr. Matthias Schmidt; Dr. James Silvius

Financial Disclosures/Conflicts of Interest

The biographies and conflicts of interest of the expert panel can be found on the Canadian Agency for Drugs and Technologies in Health (CADTH) Web site .

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Canadian Agency for Drugs and Technologies in Health (CADTH) Web site .

Availability of Companion Documents

The following is available:

- 1.5 tesla magnetic resonance imaging scanners compared with 3.0 tesla magnetic resonance imaging scanners: systematic review of clinical effectiveness. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health (CADTH); 2011 May. 74 p. Electronic copies: Available in Portable Document Format (PDF) from the CADTH Web site .

Patient Resources

None available

NGC Status

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